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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,946

Applicant(s)

BONASSA, JORGE

Examiner

ARUNDIPTA SHOME

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/5508)
- Paper No(s)/Mail Date 12-08-2005
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

This Office Action is responsive to the preliminary amendment filed on Dec. 8, 2005. As directed by the preliminary amendment, claims 1, 4, 10-13, and 17 were amended, and claim 18 was cancelled, and claims 19-25 were added. Claims 1-17 and 19-25 are pending in this application.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. There appears to be Portuguese language in Figure 1, which should be corrected. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17, and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, it is unclear how the “re-inhalation circuit” recited on line 3 is connected to the ventilation system.

Regarding Claim 3, it is unclear how the recipient can be formed by a main body, since it is unclear if these structures are distinct or the exact same structure. Also, the term “the said” in line 2 should be changed to --said--.

Regarding Claim 4, there is a lack of antecedent basis for “said base” “said reservoir” on line 3 and “the main body” on line 4. Additionally, it is unclear what the second instance of “said base” is referring to since there are two bases previously recited.

Regarding Claim 10, there is a lack of antecedent basis for a first cursor because “a second cursor” is recited on lines 2-3.

Regarding Claim 16, there is a lack of antecedent basis for “the reservoir” on line 6.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cewers (US Patent 5,694,924).

Regarding Claim 1, Cewers discloses a ventilation system (col. 11, lines 5-15). This system includes a bellows (18, see Fig. 1) disposed inside a recipient (24) provided with a manifold (the pipe connection extending from the recipient 24 to the pipes connecting to the valve 26) associated to a valve for the free flow of oxygen (valve 38, by way of tube 28, Fig. 1) inside a re-inhalation respiratory circuit, as shown in Figure 1.

Regarding Claim 2, the bellows is assembled upwardly inside the recipient, as shown in Figure 1.

Regarding Claim 11, the bellows is flexible since it can be compressed (col. 5, line 28). The bellows must be made of sterilizable material since any material can be sterilized by heating it or applying sterilizing chemicals.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924)

Regarding Claim 20, Cewers does not disclose that the bellows is made of silicone. However, it would have been obvious to one of ordinary skill in the art to modify the bellows to be made of silicone since this material is well known in the art as a highly inert material, which

is advantageous so that it does not react with any anesthetic gases passing through the ventilation device.

7. Claims 3, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Lampotang et al. (US Patent 6,131,571).

Regarding Claim 3, the recipient 24 of Cewers is formed by a main body, since it encloses the bellows (col. 4, lines 40-45). The upper end is closed by the manifold, as shown in Figure 1. Cewers does not disclose the lower end closed by a base. However, Lampotang et al. teaches a ventilating system where a bellows is enclosed by a main body 216, which has a lower base portion 218 which closes the main body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the main body of Cewers to have a base as taught by Lampotang so that a more secure connection between the bellows and the gas connector 16 is formed.

Regarding Claim 4, the bellows has an accordion like profile, as shown in Figure 1 of Cewers. The bellows must have a base with a circular opening, since Figure 1 shows that the base of the bellows is penetrated by a control rod 20 which appears to be cylindrical. The circular opening must fit into the base of the recipient 24 so that a secure connection can be formed between the bellows and the base of recipient. Cewers does not disclose that the base is fixed by way of a pressure screw on the main body. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect to base to the main body with a pressure screw since such screws are well known in the mechanical art to provide reliable connections between rigid members.

Regarding Claim 6, the base of the recipient as noted with respect to claim 3 has a first connection to couple to the re-inhalation tube 10 of Cewers, and a second connection connected to the manifold via tube 28, both shown in Figure 1.

8. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Lampotang et al. (US Patent 6,131,571) as applied to claim 4 above, further in view of Anderson et al. (US Patent 5,381,997).

Regarding Claim 5, Cewers does not disclose a hard disk with a ring on the accordion shaped bellows. However, Anderson et al. teaches a venting system with a bellows 46 that has a disk 44 secured by a screw 50 and an O-ring 52. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bellows of Cewers to have a hard disk secured via a screw and O-ring as taught by Anderson et al. so that the top of the bellows is secured to the control rod 20. In this case, the head of the screw would be a hard disk, and the screw/hard disk is fitted under pressure by way of the O-ring. See col. 3, lines 30-40 of Anderson et al.

Regarding Claim 12, Cewers/Anderson discloses a bellows with a disk on top, but does not disclose a bellows with disk on top of the bellows comprising aluminum. However it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hard disk located on top of the bellows as noted with respect to claim 5 to be made of aluminum, since aluminum is well known in the art as a lightweight material and a lighter disk will decrease the amount of pressure needed to expand the bellows.

9. Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Sato et al. (US Patent 6,302,149).

Regarding Claim 7, Cewers does not disclose a manifold with an exhaling valve and a release valve. Sato et al. teaches a solenoid valve manifold as shown in Figures 1 and 2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Cewer's valve and manifold with the solenoid valve manifold as taught by Sato so that the ventilator device can control the opening and closing of the valves in the manifold. The manifold can have two solenoid valves contained within (abstract lines 4-8), so one valve would be an exhaust valve and one would be a release valve. Since Cewers discloses two bellows, two valves would be advantageous to control flow from each bellows.

10. Claims 15-17 and 23- 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Sato et al. (US Patent 6,302,149) as applied to claim 7 above, further in view of Garafalo (5,810,041).

Regarding Claim 15, Cewers/Sato does not disclose an exhalation valve with an air nozzle and a flexible diaphragm activated by pressure of an inlet channel. Garafalo teaches a valve with an air nozzle 28 that is provided with a flexible diaphragm 24 that is activated by the pressure of an inlet channel (col. 4 line 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add this valve as taught by Garafalo with the air nozzle and flexible diaphragm to the solenoid valve manifold of Cewers/Sato, as noted with respect to claim 7 (either upstream or downstream of the solenoid valves) to act as an exhalation valve so that a user can control the pressure that is transmitted from the bellows through the reinhalation circuit of the ventilating system.

Cewers/Sato does not disclose a release valve with an air nozzle and a flexible diaphragm activated by pressure of an inlet channel. Garafalo teaches a valve with an air nozzle 28 that is

provided with a flexible diaphragm 24 that is activated by the pressure of an inlet channel (col. 4 line 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add this valve as taught by Garafalo with the air nozzle and flexible diaphragm to the valve manifold of Cewers/Sato, as noted with respect to claim 7 (either upstream or downstream of the solenoid valves) to act as an release valve so that a user can control the pressure that is transmitted from the bellows through the reinhalation circuit of the ventilating system.

Regarding Claim 16, the valve of Garafalo as noted with respect to claim 15 has a cursor 18, the upper end is supported on a spring 14 over an air nozzle 28. The air nozzle 28 is located in the valve which is part of the manifold as noted with respect to claim 7. The lower end of the cursor is supported on a flexible diaphragm 24 which is provided at its opposite side with a second cursor (the sides of stopper 20 parallel to the cursor 18) disposed at the end of a disk (disk shaped portion of 20) that projects into a reservoir 22.

Regarding Claim 17, Cewers/Sato does not disclose a release valve with an air nozzle and a flexible diaphragm activated by pressure of an inlet channel. Garafalo teaches a valve with an air nozzle 28 that is provided with a flexible diaphragm 24 that is activated by the pressure of an inlet channel (col. 4 line 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add this valve as taught by Garafalo with the air nozzle and flexible diaphragm to the valve manifold of Cewers/Sato, as noted with respect to claim 7 (either upstream or downstream of the solenoid valves) to act as an release valve so that a user can control the pressure that is transmitted from the bellows through the reinhalation circuit of the ventilating system.

Regarding Claims 23-25, Cewers does not disclose that the flexible diaphragm is made of silicone. However, it would have been obvious to one of ordinary skill in the art to modify the diaphragm to be made of silicone since this material is well known in the art as a highly inert material, which is advantageous so that it does not react with any anesthetic gases passing through the ventilation device.

11. Claims 8, 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Garafalo (US Patent 5,810,041).

Regarding Claim 8, Cewers does not teach the valve for the free flow of oxygen having two stages. Garafalo teaches a pressure regulator valve with a pilot stage (chamber 2) and a main stage (chamber 22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the valve 38 of Cewers with the valve as taught by Garafalo so that a user can control the pressure that is transmitted through the reinhalation circuit of the ventilating system.

Regarding Claim 10, Garafalo teaches the main stage is formed by an oxygen inlet channel 28 and a second cursor 32 supported over a spring 30, the second cursor and spring being activate by the movement of a diaphragm 24 by means of pressure in a chamber 2 that separates both stages.

Regarding Claim 19, The combination of Cewers/Garafalo as noted with respect to claim 10 discloses a diaphragm 24 (col. 3, line 40 of Garafalo). Garafalo does not disclose that the diaphragm is a silicone diaphragm. However, it would have been obvious to one of ordinary skill in the art to modify the diaphragm to be made of silicone since this material is well known in the

art as a highly inert material, which is advantageous so that it does not react with any anesthetic gases passing through the ventilation device.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Garafalo (US Patent 5,810,041) as applied to claim 8 above, further in view of Hiigler (US Patent 4,561,632).

Regarding Claim 9, the pilot stage of the valve of Garafalo has a manual activation valve (valve seat 12 and shutoff element 10, controlled by manual plug 6). The valve is constituted by a cursor (flanges of plug 6) supported over a spring (14) which is activated by a manual key (6).

Cewers/Garafalo does not disclose a solenoid connected to the inlet channel 38 of the pilot stage of the valve of Garafalo. Hiigler teaches a solenoid valve. It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a solenoid valve as taught by Hiigler connected to the inlet channel of the valve of Garafalo so that the ventilator of Cewers, which has a controller, can control the opening and closing of a valve which allows the ventilator to control flow through the tube 6.

13. Claims 13, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Lampotang et al. (US Patent 6,131,571), as applied to claim 3 above, further in view of Hedenberg (US Patent 6,263,873).

Regarding Claim 13, Cewers/Lampotang discloses a bellows but does not disclose a transparent bellows. Hedenberg teaches a bellow for a ventilator system that has a transparent main body for enclosing the bellows (col. 2, lines 60-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the main body of Cewers with a transparent main body as taught by Hedenberg because Hedenberg teaches that such

containers are usually transparent to allow the a user to view the movement of the bellows (col. 1, lines 40-45).

Regarding Claim 21, Cewers/Hedenberg does not disclose that the transparent recipient is made of acrylics. However, it would have been obvious to one of ordinary skill in the art to modify the recipient/main body to be made of acrylics since this material is well known in the art as a highly durable transparent material, which is advantageous because it provides a strong and reliable transparent window to enclose the bellows.

Regarding Claim 22, Cewers/Hedenberg does not disclose that the transparent recipient is made of polycarbonate. However, it would have been obvious to one of ordinary skill in the art to modify the recipient/main body to be made of polycarbonate since this material is well known in the art as a highly durable transparent material, which is advantageous because it provides a strong and reliable transparent window to enclose the bellows.

14. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Cewers (US Patent 5,694,924) in view of Lampotang et al. (US Patent 6,131,571) as applied to claim 3 above, further in view of Braatz et al. (US Patent 5,651,357).

Regarding Claim 14, Cewers does not disclose that the manifold as noted with respect to claim 1 has indentations that fit in pins. Braatz discloses a mechanical connection for a gas container that uses pins and indentations to connect the container to a gas delivery apparatus. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the manifold of Cewers to connect to the main body with indentations on the manifold and pins on the main body as taught by Braatz et al. This is because a pin and indentation type of

connection is well known in the art, and would offer the advantage of allowing a user to uncouple the manifold to permit access to the bellows in case the bellows needed to be repaired, inspected, or replaced.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Heinonen (US Patent 5,490,499) is cited to show a ventilating system with a bellows, control unit, patient circuit, and various valves in the system.

Levy (US Patent 4,340,044) is cited to show another similar ventilating system with a bellows.

McGinnis (US Patent 4,823,828) is cited to show a valve with a spring and diaphragm for respiratory applications.

Jones (EP 0 375 281) is cited to show a two stage demand valve with a spring and diaphragm.

Ekstrom (US Patent 3,724,482) is cited to show a two stage breathing valve.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 8:30am to 6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arun Shome/
Examiner, Art Unit 3771
Oct. 14, 2008

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